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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ANDERSON, GREGORY A	

ART UNIT	PAPER NUMBER
3773	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/627,960	CHERNOMORSKY ET AL.	
	Examiner	Art Unit	
	GREGORY A. ANDERSON	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10,12,14-19,21-33,40-57,59-62,64-69,74-78,83-85,87-92,96,97,102,103,137-154,156-165 and 169-175.* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-7,10,12,14-19,21-33,40-57,59-62,64-69,74-78,83-85,87-92,96,97,102,103,137-154,156-165 and 169-175.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 12, 14-19, and 21-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Vyakarnam et al. 6,333,029.

Regarding claim 1: Vyakarnam et al. discloses an implant comprising: a first portion including a first porous matrix defining a first controlled pore architecture, and a second portion (Col. 17 ll. 9-10) coupled to the first portion, the second portion including a second porous matrix defining a second controlled pore architecture that is different from the first controlled pore architecture to cause the second portion to swell in a different manner than the first portion when the post-biopsy cavity treatment implant is implanted, at least one of the first and second portions including collagen (Col. 17 ll. 31-34) and at least one of the first and second portions defining a closed internal reservoir configured to contain at least one of a dye, a pigment and a therapeutic agent (Col. 17 ll. 54-59).

Regarding claim 2: Vyakarnam et al. further discloses the second portion swells faster than the first portion when the implant is implanted (Col. 5 ll. 66-67).

Regarding claim 3: Vyakarnam et al. further discloses the second portion swells to a greater extent than the first portion when the implant is implanted (Col. 5 ll. 66-67, the extent of swelling is inherent to pore size).

Regarding claim 4: Vyakarnam et al. further discloses the first controlled pore architecture differs from the second controlled pore architecture with respect to at least one of: pore density, pore shape, pore orientation and pore dimensions (Col. 5 ll. 54-67, Col. 6 ll. 1-29).

Regarding claim 5: Vyakarnam et al. further discloses at least one of the first and second portions includes a radiopaque material disposed therein (Col. 19. ll. 17-19).

Regarding claim 12: Vyakarnam et al. further discloses at least one of the first and second portions is biodegradable (Col. 2 ll. 31-34).

Regarding claim 14: Vyakarnam et al. further discloses the first and second portions include at least one of a polylactide (PLA), a polyglycolide (PGA), a poly(lactide-co-glycolide) (PLGA), a polyglyconate, a polyanhydride, PEG, cellulose, a gelatin, a lipids, a polysaccharide, a starches and a polyorthoesters (Col. 6 ll. 30-45, Col. 9 l. 30-Col. 10 l. 24).

Regarding claim 15: Vyakarnam et al. further discloses the first and second portions are configured so as to form a laminar structure (Col. 5 ll. 54-56).

Regarding claim 16: Vyakarnam et al. further discloses the first portion defines a first surface and wherein the second portion defines a second surface that faces the first surface to define an interface between the first and second portions (Fig 9c).

Regarding claim 17: Vyakarnam et al. further discloses the interface is visualizable under ultrasound when the post-biopsy cavity treatment implant is implanted (Col. 19 ll. 17-19).

Regarding claim 18: Vyakarnam et al. further discloses at least the first portion includes a plurality of fibers (Col. 6 ll. 27-29).

Regarding claim 19: Vyakarnam et al. further discloses the first portion forms an inner core and wherein the second portion forms an outer shell disposed at least partially around the first portion (Col. 17 ll. 54-61).

Regarding claim 21: Vyakarnam et al. further discloses the internal reservoir is configured to deliver the at least one of dye, pigment and therapeutic agent through elution when the implant is implanted (Col. 17 ll. 54-67).

Regarding claim 22: Vyakarnam et al. further discloses the internal reservoir is configured to deliver the at least one of dye, pigment and therapeutic agent at a first rate when the reservoir is breached and at a second rate that is lower than the first rate when the reservoir is not breached (Col. 18 ll. 34-45).

Regarding claim 23: Vyakarnam et al. further discloses a third portion, the third portion being radiopaque (Col. 6 ll. 1-4, Col. 19 ll. 17-19).

Regarding claim 24: It is notoriously well known in the art to use metal to make an object radiopaque.

Regarding claim 25: Vyakarnam et al. further discloses a third portion including a third porous matrix defining a third controlled pore architecture, the first, second and

third portions collectively defining a predetermined pore density gradient (Col. 5 l. 54-Col. 6 l. 29).

Regarding claim 26: Vyakarnam et al. further discloses the second portion is configured to have a second crosslinking density and wherein the first portion is configured to have a first crosslinking density that is greater than the second crosslinking density (Col 5 ll. 54-56, inherent to the change in pore size).

Regarding claim 27: Vyakarnam et al. further discloses the second portion is configured to swell to a greater degree than the first portion when the implant is implanted (Col. 5 ll. 54-56, inherent to pore size).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 6, 74-78, 84, 85, 87-92, 96, and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vyakarnam et al. in view of Pfeil et al. 4,135,935.

Regarding claims 6 and 74: Vyakarnam et al. discloses the invention essentially as claimed as discussed in claim 1 above. Vyakarnam et al. further discloses the device containing chemotherapeutic agents for the treatment of cancer. It is well known in the art to include dyes or pigments in implanted objects to facilitate visualization.

However, Vyakarnam et al. does not disclose a radioactive material disposed within the device.

Pfeil et al. discloses a radioactive material to be used as an implant in the body (Abstract).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Vyakarnam et al. with the radioactive material of Pfeil et al. in order to facilitate the treatment of cancer as taught by Pfeil et al. (Abstract).

Regarding claims 75-78, 84, 85, 87-92, 96, and 97: Vyakarnam et al. discloses the limitations of the claims as discussed in the 102(b) rejections above regarding claims 2-5, 12, 14-19, and 21-24.

5. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vyakarnam et al. in view of Gordon 4,622,952.

Vyakarnam et al. discloses the invention essentially as claimed as discussed above.

However, Vyakarnam does not disclose a paramagnetic material within the device.

Gordon discloses using paramagnetic materials (Claim 15).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Vyakarnam et al. with the paramagnetic materials of Gordon in order to aide visualization of tumors for cancer treatment.

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vyakarnam et al. in view of Meade et al. 6,673,333.

Vyakarnam et al. discloses the invention essentially as claimed as discussed above.

However, Vyakarnam et al. does not disclose using a contrast media.

Meade et al. discloses using a contrast media (Col. 2 ll. 1-14).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Vyakarnam et al. by adding the contrast agent of Meade et al. in order to facilitate the imaging of cancerous parts of the body.

7. Claims 28-30, 40-43, 49-57, 59-62, 64-66, 137-140, 146-154, 156-162, 169-172 and 174 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vyakarnam et al. in view of Chvapil 4,193,813.

Regarding claims 28-30, 40, 64-66, 137, 169, and 170-172: Vyakarnam et al. discloses an implant comprising first, second, and third sections, each section comprising a controlled pore architecture that is different from the others (Col. 5 l. 54-Col. 6 l. 29). Vyakarnam et al. further discloses the implant comprising an internal reservoir containing therapeutic agents (Col. 17 ll. 54-60). Vyakarnam et al. further discloses the inclusion of collagen (Col. 17 ll. 31-34).

However, Vyakarnam et al. does not disclose the first and second portions including a crosslinking density that is controlled through adding a selected amount of bifunctional reagent to the collagen, the reagent being an aldehyde that contains glutaraldehyde.

It is well known in the art to modify porous materials by crosslinking as evidenced by Chvapil. Chvapil discloses crosslinking collagen with glutaraldehyde (Col. 9 ll. 3-26).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Vyakarnam et al. by using glutaraldehyde to

crosslink the collagen in order to alter the characteristics of the porous material as taught by Chvapil (Col. 9 ll. 6-8).

Regarding claims 41-43, 49-57, 59-62, 138-140, 146-154, 156-159 and 175: Vyakarnam et al. discloses the limitations of the claims as discussed in the 102(b) rejections above regarding claims 2-5, 12, 14-19, and 21-24.

8. Claims 31-33, 40, 67-69, 137, 163-165 and 173 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vyakarnam et al. in view of Dean, Jr. et al. 4,861,714.

Vyakarnam et al. discloses an implant comprising first, second, and third sections, each section comprising a controlled pore architecture that is different from the others (Col. 5 l. 54-Col. 6 l. 29). Vyakarnam et al. further discloses the implant comprising an internal reservoir containing therapeutic agents (Col. 17 ll. 54-60). Vyakarnam et al. further discloses the inclusion of collagen (Col. 17 ll. 31-34).

However, Vyakarnam et al. does not disclose the first and second portions including a crosslinking density that is controlled by an application of energy to the collagen that includes dehydrothermal processing and exposure to cyanamide.

It is well known in the art to modify porous materials by crosslinking as evidenced by Dean, Jr. et al.. Dean, Jr. et al. discloses exposing collagen sponges to dehydrothermal treatment and cyanamide as a crosslinking agent (Col. 10 ll. 14-21).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Vyakarnam et al. with the crosslinking of Dean, Jr.

et al. in order to provide a sponge that is biocompatible and stable for a period of time on the order of months as disclosed by Dean, Jr. et al. (Col. 2 ll. 50-54).

9. Claims 44 and 141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vyakarnam et al. in view of Chvapil as applied to claims 40 and 137above and further in view of Pfeil et al..

Vyakarnam et al. in view of Chvapil discloses the invention essentially as claimed as discussed in claim 40 above. Vyakarnam et al. further discloses the device containing chemotherapeutic agents for the treatment of cancer.

However, Vyakarnam et al. in view of Chvapil does not disclose a radioactive material disposed within the device.

Pfeil et al. discloses a radioactive material to be used as an implant in the body (Abstract).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Vyakarnam et al. in view of Chvapil with the radioactive material of Pfeil et al. in order to facilitate the treatment of cancer as taught by Pfeil et al. (Abstract).

10. Claims 45 and 142 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vyakarnam et al. in view of Chvapil as applied to claims 40 and 137 above and further in view of Gordon.

Vyakarnam et al. in view of Chvapil discloses the invention essentially as claimed as discussed above.

However, Vyakarnam in view of Chvapil does not disclose a paramagnetic material within the device.

Gordon discloses using paramagnetic materials (Claim 15).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Vyakarnam et al. in view of Chvapil with the paramagnetic materials of Gordon in order to aide visualization of tumors for cancer treatment.

11. Claims 46-48 and 143-145 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vyakarnam et al. in view of Chvapil as applied to claims 40 and 137 above and further in view of Meade et al..

Vyakarnam et al. in view of Chvapil discloses the invention essentially as claimed as discussed above.

However, Vyakarnam et al. in view of Chvapil does not disclose using a contrast media.

Meade et al. discloses using a contrast media (Col. 2 ll. 1-14).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Vyakarnam et al. in view of Chvapil by adding the contrast agent of Meade et al. in order to facilitate the imaging of cancerous parts of the body. Further it is well known in the art to use a dye or pigment as a contrast medium to suit the type of imaging.

12. Claim 83 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vyakarnam et al. in view of Pfeil et al. as applied to claim 74 above and further in view of Meade et al..

Vyakarnam et al. in view of Pfeil et al. discloses the invention essentially as claimed as discussed above.

However, Vyakarnam et al. in view of Pfeil et al. does not disclose using a contrast media.

Meade et al. discloses using a contrast media (Col. 2 ll. 1-14).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Vyakarnam et al. in view of Pfeil et al. by adding the contrast agent of Meade et al. in order to facilitate the imaging of cancerous parts of the body.

13. Claims 102 and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vyakarnam et al. in view of Pfeil et al. as applied to claim 74 above and further in view of Dean, Jr. et al..

Vyakarnam et al. in view of Pfeil et al. disclose the invention essentially as claimed as discussed in claim 74 above.

However, Vyakarnam et al. in view of Pfeil et al. does not disclose the first and second portions including a crosslinking density that is controlled by an application of energy to the collagen that includes dehydrothermal processing and exposure to cyanamide.

It is well known in the art to modify porous materials by crosslinking as evidenced by Dean, Jr. et al.. Dean, Jr. et al. discloses exposing collagen sponges to dehydrothermal treatment and cyanamide as a crosslinking agent (Col. 10 ll. 14-21).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Vyakarnam et al. in view of Pfeil et al. with the crosslinking of Dean, Jr. et al. in order to provide a sponge that is biocompatible and stable for a period of time on the order of months as disclosed by Dean, Jr. et al. (Col. 2 ll. 50-54).

Response to Arguments

14. Applicant's arguments filed 13 January 2009 have been fully considered but they are not persuasive. Applicant argues that the Vyakarnam et al. reference does not disclose a closed internal reservoir configured to contain at least one of a dye, pigment, and a therapeutic agent. Examiner disagrees; the Vyakarnam et al. reference discloses loading therapeutic agents into the foam after it is formed (see Col. 17 ll. 54-59) and as such the agent would be contained within the pores of the foam, the pores being individually enclosed reservoirs.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGORY A. ANDERSON whose telephone number is (571)270-3083. The examiner can normally be reached on Mon-Thurs 9:30am-3:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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